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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/896,805	07/18/97	MARTIN	G 3359-4005US1

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QM31/1005

EXAMINER

NGUYEN, T

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 10/05/98

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
08/896,805

Applicant(s)  
MARTIN et al.

Examiner  
Tram Nguyen

Group Art Unit  
3738



☐ Responsive to communication(s) filed on \_\_\_\_\_.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-40 is/are pending in the application.

Of the above, claim(s) 30-40 is/are withdrawn from consideration.

☒ Claim(s) 28 and 29 is/are allowed.

☒ Claim(s) 1-22 and 24-26 is/are rejected.

☒ Claim(s) 23 and 27 is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-29, drawn to a stent-graft , classified in class 623, subclass 1.
- II. Claim 30, drawn to a method of deploying a stent-graft, classified in class 128, subclass 898.
- III. Claims 31-40, drawn to a method of making a stent-graft, classified in class 600, subclass 36.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, as is evident by the fact that the method of Group II does not require the particulars of the product of Group I to proceed.

3. Inventions Group I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the

instant case the product as claimed can be made by another and materially different process, as is evident by the fact that the method of Group III does not require the particulars of the product of Group I and can therefore produce a materially different product than that of Group I.

4. Inventions Group III and II are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Michael Marcus on September 25, 1998 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-29. Affirmation of this election must be made by applicant in replying to this Office action. Claims 30-40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Information Disclosure Statement***

8. The information disclosure statement filed February 25, 1998 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because pending U.S. patent applications are not considered *published* prior references. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the following reasons:

a. Regarding claim 1, applicant recites "said member" in line 6; however, applicant previously recited both a stent member and a tubular graft member. The examiner is therefore unclear as to which of these member the "said member" in line 6 refers.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

12. Claims 1-3, 14-16, 21, 22, 24, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Winston et al. (U.S. Patent No. 5,723,003), for the following reasons:

- a. With respect to claim 1, see Figure 9 for a stent-graft comprising:
  - a stent member (34) having an inner surface and an outer surface;
  - a generally tubular graft member (10); and
  - a ribbon (14) covering only a portion of at least one of the inner and outer surfaces of the member and securing the stent member and graft member to one another.
- b. With respect to claims 2 and 3, see Figure 9 wherein the stent member (34) comprises multiple tubular members.
- c. With respect to claim 14, col. 4, lines 1-3 wherein the graft member has an average thickness of less than about 0.006 inch.
- d. With respect to claim 15, see col. 6, lines 54-61 wherein the ribbon has an average thickness of less than about 0.005 inch.
- e. With respect to claim 16, see col. 4, lines 26-28 wherein the graft member comprises porous expanded PTFE.

f. With respect to claim 21, see Figure 9 wherein the ribbon has a generally flat portion that faces the graft member.

g. With respect to claim 22, see Figure 9 wherein the ribbon (14) interconnects less than entirely one of said inner and outer surfaces of the graft member to the stent member (i.e., the ribbon 14 does not completely cover graft 10).

h. With respect to claim 24, see Figure 9 wherein the ribbon has a generally flat portion that faces the graft member.

i. With respect to claim 25, see Figure 9 wherein the stent member is tubular, the stent and graft members are coaxial, and the graft member is disposed in the stent member.

13. Claims 1, 4, 7, 9-13, 21, and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by An et al. (U.S. Patent No. 5,545,211), for the following reasons:

a. With respect to claim 1, see Figure 5 for a stent-graft comprising:

a stent member (10) having an inner surface and an outer surface;

a generally tubular graft member (13); and

a ribbon (14) covering only a portion of at least one of the inner and outer surfaces of the member and securing the stent member and graft member to one another.

b. With respect to claim 4, see Figure 3 wherein the stent member (10) comprises a first member having undulations (zig zags) and being arranged in a helical configuration with multiple turns (as shown in Figure 2).

c. With respect to claim 7, see Figure 5 wherein the ribbon covers a portion of the undulations.

d. With respect to claim 9, see Figures 2 and 3 wherein a linking member (9) is threaded between adjacent turns to maintain undulations in adjacent turns generally in phase with one another.

e. With respect to claim 10, see Figure 3 wherein a number of undulations are configured to permit unrestrained movement of an undulation generally in-phase.

f. With respect to claim 11, see Figure 3 wherein the undulations appear generally sinusoidal.

g. With respect to claims 12 and 13, see Figure 2 wherein the ribbon (9) has a width less than about two-thirds, or even three-fourths, the average amplitude of one of the undulations.

h. With respect to claim 21, see Figure 3 wherein the ribbon has a generally flat portion that faces the graft member.

i. With respect to claim 26, see Figure 3 wherein the stent member has  
a first member (10) and a second member (9), the first member being arranged in a helical configuration with multiple helical turns, the second member coupling adjacent helical turns;  
a generally tubular graft member (13), the graft member surrounding at least a portion of the stent member; and

a coupling member coupling less than entirely an inner surface of the stent member.

14. Claims 1, 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Tartaglia et al. (U.S. Patent No. 5,637,113), for the following reasons:

a. With respect to claim 1, see Figure 5 for a stent-graft comprising:

a stent member (72) having an inner surface and an outer surface;



- a generally tubular graft member (84); and
- a ribbon (80) covering only a portion of at least one of the inner and outer surfaces of the member and securing the stent member and graft member to one another.
- b. With respect to claim 19, see col. 5, lines 18-36 wherein the stent member comprises nitinol.
- c. With respect to claim 20, see col. 6, lines 54-61 wherein the ribbon is adhesively bonded to the graft member.

***Allowable Subject Matter***

15. Claims 28 and 29 are allowed.
16. Claims 5, 6, 8, 13, 17, and 18 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
17. Claims 23 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

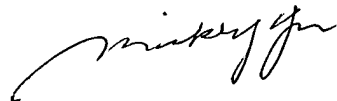
***Conclusion***

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No.'s 4,502,159; 5,282,824; 5,370,691; 5,405,378; 5,554,181; 5,662,713; and, 5,749,825 all show various features of the claimed invention.

should be directed to Tram Nguyen whose telephone number is (703) 308-0804. The examiner can normally be reached on Monday - Friday from 9:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu, can be reached at (703) 308-2672. The fax phone number for this group is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceedings should be directed to the group receptionist whose telephone number is (703) 308-0858.



Mickey Yu  
Supervisory Patent Examiner  
Group 3700

*TAN*

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September 30, 1998